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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/920,318	07/31/2001	Kathleen M. Smith	DX01136K	5031

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DNAX RESEARCH, INC.
LEGAL DEPARTMENT
901 CALIFORNIA AVENUE
PALO ALTO, CA 94304

EXAMINER

NICHOLS, CHRISTOPHER J

ART UNIT	PAPER NUMBER
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1647

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DATE MAILED: 07/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/920,318

Applicant(s)

SMITH ET AL.

Examiner

Christopher Nichols, Ph.D.

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,6 and 8-13 is/are pending in the application.
- 4a) Of the above claim(s) 1-3 and 6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments, And/Or Claims

1. The amendments filed 29 May 2003 (Paper No. 14) has been received and entered in full. Claims 4, 5, and 7 have been cancelled and claims 8-13 have been added. Claims 1-3 and 6 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Claims 8-13 are under examination.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objections And/Or Rejections

3. The objections to the specification regarding sequences and informalities as set forth at pp. 2-3 ¶4-5 of the previous Office Action (Paper No. 13, 27 February 2003) are *withdrawn* in view of Applicant's amendments (Paper No. 14, 29 May 2003).
4. All previous rejections of claims 4, 5, and 7 under 35 U.S.C. §112 ¶1 as set forth at pp. 3-6 ¶6-13 of the previous Office Action (Paper No. 13, 27 February 2003) are *withdrawn* in view of Applicant's cancellation of said claims (Paper No. 14, 29 May 2003).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for

Art Unit: 1647

patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 8, 11, 12, and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by US 2002/0138860 A1 (26 September 2002) Cook et al. (claims priority to provisional application No. 60/152866 filed 8 September 1999). US 2002/0138860 teaches a small molecule that blocks the function of CCR6 or MIP-3 α thus meeting the limitations of claims 11 ([0009]). US 2002/0138860 teaches antibodies against CCR6 and MIP-3 α thus meeting the limitations of claims 12 and 13 ([0009], [0049], [0054], [0090]-[0092]). US 2002/0138860 teaches the use of antibodies against CCR6 and MIP-3 α for use in treating inflammatory bowel disease thus meeting the limitations of claims 8 and 11 ([0007], [0064]).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Art Unit: 1647

6. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0138860 A1 (26 September 2002) Cook et al. (claims priority to provisional application No. 60/152866 filed 8 September 1999) and taken with MacDermott *et al.* (February 1998) "The Central Role of Chemokines (Chemotactic Cytokines) in the Immunopathogenesis of Ulcerative Colitis and Crohn's Disease." Inflammatory Bowel Diseases 4(1): 54-67.

7. US 2002/0138860 teaches a small molecule that blocks the function of CCR6 or MIP-3 α thus meeting the limitations of claims 11 ([0009]). US 2002/0138860 teaches antibodies against CCR6 and MIP-3 α thus meeting the limitations of claims 12 and 13 ([0009], [0049], [0054], [0090]-[0092]). US 2002/0138860 teaches the use of antibodies against CCR6 and MIP-3 α for use in treating inflammatory bowel disease thus meeting the limitations of claims 8 and 11 ([0007], [0064]).

8. US 2002/0138860 does not teach, however, the use of anti-CCR6 or anti- MIP-3 α for use in treating inflammatory bowel diseases such as ulcerative colitis and Crohn's Disease.

9. MacDermott *et al.* (February 1998) teaches:

The development of selective inhibitors for chemokines will be of great interest as potential therapeutic strategies in ulcerative colitis and Crohn's disease. Agents that inhibit chemokine synthesis, or that block chemokine binding to serpentine family receptors on granulocytes, monocytes, and lymphocytes, may have the potential of inhibiting the process of granulocyte and/or monocytes and/or lymphocyte migration into mucosa and submucosa of involved intestine in patients with IBD, which in turn could diminish the severity of the inflammatory response and, thus, clinical disease activity." (pp. 63)

10. Thus it would have been obvious to a person of ordinary skill in the art at the time of the invention to use the anti-CCR6 and anti-MIP3 α antibodies as taught by US 2002/0138860 for

Art Unit: 1647

use in treating inflammatory bowel diseases in ulcerative colitis and Crohn's disease thus meeting the limitations of claims 8-11.

11. A person of ordinary skill in the art at the time of the invention would have been motivated to using US 2002/0138860's antibodies to treat ulcerative colitis and Crohn's disease because they are members of the inflammatory bowel disease genus [MacDermott *et al.* pp. 63].

12. A person of ordinary skill in the art at the time of the invention would have a reasonable expectation of success because the mechanism of elevated chemokine receptors and their ligands occur in ulcerative colitis and Crohn's disease, a genus to which CCR6 and MIP-3 α belong [MacDermott *et al.* pp. 61].

13. Thus the invention as a whole was *prima facie* obvious over the prior art.

Summary

14. No claims are allowed.

15. The following articles, patents, and patent publications were found by the Examiner during the art search and are here made of note:

- a. WO 00/46248 (10 August 2000) Oldham *et al.*
- b. WO 03/026404 A2 (3 April 2003) Brennan *et al.*

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

Art Unit: 1647

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Art Unit: 1647

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is 703-305-3955. The examiner can normally be reached on Monday through Friday, 8:00AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Gary Kunz, Ph.D.** can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. The fax phone numbers for the customer service center is 703-872-9305

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

CJN
June 28, 2003

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER